FEB 2 1 2014

510(k) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent:

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Submitter of 510(k):

Infinium Medical
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Date of Summary: June 8, 2013

Trade/Proprietary Name: Omni Series Patient Monitors

Common Name: Patient Physiological Monitor (without Arrhythmia Detection or Alarms)

Classification Name: Monitor, physiological, patient (without Arrhythmia detection or alarms)

Device Class: II

Device Panel: Cardiovascular

Product Code: MWI

Subsequent Product Codes:

Regulation Number	Description	Product Code	Applicable Monitor
870.2340	Electrocardiograph	DPS	All
870.1130	Noninvasive Blood Pressure Measurement	DXN	All
870.2700	Oximeter	DQA	All
868.2375	Breathing frequency	BZQ	All

	monitor		
880.2910	Clinical Electronic Thermometer	FLL	All
870.1110	Blood Pressure Computer	DSK	OMNI, OMNI II, OMNI III
870.1425	Programmable diagnostic computer	DQK	All
870.1435	Single-function, preprogrammed diagnostic computer	DXG	OMNI II, OMNI III
868.1400	Carbon dioxide gas analyzer	CCK	All

Intended Use:

OMNI

The purpose and function of the OMNI patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

OMNI II

The purpose and function of the OMNI II patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

OMNI III

The purpose and function of the OMNI III patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

OMNI Express

The purpose and function of the OMNI Express patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3 to 5 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- Anesthetic agents

The target population is for adult, neonate and pediatric patients.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Device Description:

OMNI
The OMNI monitor is a comprehensive monitoring system with four, six or eight traces compiling, and processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.
The OMNI monitor can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

OMNI II
The OMNI II monitor is a comprehensive monitoring system with four, six or eight traces compiling, and processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.
The OMNI II monitor can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

OMNI III
The OMNI III monitor is a comprehensive monitoring system with eight traces compiling, and processing, analyzing and displaying data from up to six different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.
The OMNI III can be powered by an internal battery pack that provides 1 hour of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

OMNI Express
The OMNI EXPRESS monitor is a comprehensive monitoring system with two or three traces compiling, and processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.
The OMNI EXPRESS monitor can be powered by an internal battery pack that provides 2 hours of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

Substantial Equivalence:

The OMNI patent monitor is substantial equivalent in intended use and similar technological characteristics of IBP, $C0_2$, Anesthetic Agents, and 12 Lead ECG to the Datascope Corp. Spectrum™ Monitor under K062098.

The OMNI II and OMNI III are substantially equivalent to the Datascope Corp. Spectrum™ Monitor under K062098 in intended use and similar technological characteristics of IBP, CO_2, Anesthetic Agents, 12 Lead ECG and Cardiac output .

The OMNI Express is substantially equivalent to the Datascope Corp. Spectrum™ Monitor under K062098 as it pertains to CO_2 and Anesthetic Agents.

The OMNI Patient Monitors are substantially equivalent to the previously cleared OMNI Patient Monitors as it pertains to previously cleared technological characteristics and performance. A comparison of these technological characteristics is included in the submission.

Device	Clearance Number	Substantial Equivalence to
Datascope Corp – Spectrum ™ Monitor	K062098	Intended use and functions of IBP, CO2, Cardiac Output, Anesthetic Agents
OMNI Patient Monitor	K112329	Intended use Previously Cleared Technological Characteristics and Performance
OMNI II Patient Monitor	K103737	Intended use

		Previously Cleared Technological Characteristics and Performance
OMNI III Patient Monitor	K101052	Intended use Previously Cleared Technological Characteristics and Performance
OMNI Express Patient Monitor	K1037268	Intended use Previously Cleared Technological Characteristics and Performance

Rational for Substantial Equivalence:

The testing completed in the previously cleared submissions along with the additional testing completed demonstrates that the OMNI Series Patient Monitors exhibit comparable mechanical and functional characteristics to the predicate devices in addition to being biocompatible acceptable. Based on those characteristics, the Infinium OMNI Patient Monitors are substantially equivalent to the predicate devices in safety and effectiveness in addition to being intended for the same uses.

Summary of Non-Clinical Data:

The OMNI series patient monitors underwent bench testing according to several different performance standards. Below is a chart of the different testing that was completed.

Patient Monitor	Performance Test	Standard of Compliance
OMNI	IBP	BS EN 60601-2-34:2000
	ECG	ANSI/AAMI EC13:2002/(R)2007
OMNI II, OMNI III	IBP	BS EN 60601-2-34:2000
	ECG	ANSI/AAMI EC13:2002/(R)2007
	Cardiac Output	No Standard

Based on the conclusions of each of these tests it is determined that the OMNI Patient Monitors are safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Infinium Medical
c/o Mr. John O'Brien
445 Apollo Beach Blvd
Apollo Beach, FL 33572 US

Re: K132229
Trade/Device Name: Omni Patient Monitors
(Models: Omni, Omni II, Omni III and Omni Express)
Regulation Number: 21 CFR 870.2340
Regulation Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: January 13, 2014
Received: January 16, 2014

Dear Mr. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: OMNI Patient Monitor

The purpose and function of the OMNI patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients:

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for Use

510(k) Number (if known):

Device Name: OMNI II Patient Monitor

The purpose and function of the OMNI II patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known):

Device Name: OMNI III Patient Monitor

The purpose and function of the OMNI III patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- Cardiac Output
- IBP
- Anesthetic agents

The target population is for adult, neonate and pediatric patients with the exception of:

- Cardiac Output for which the target population is adult only.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known):

Device Name: OMNI Express Patient Monitor

The purpose and function of the OMNI Express patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3 to 5 lead measurements
- Heart Rate
- NIBP(systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)
- CO_2
- Anesthetic agents

The target population is for adult, neonate and pediatric patients:

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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